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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MYERS, CARLA J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/759,783	LO ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-56 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-56 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESTRICTION

1. Prior to setting forth the restriction requirement, it is pointed out that Applicants have presented claims 1-56 in improper Markush format. See Ex parte Markush, 1925 C.D. 126 and In re Weber, 198 USPQ 334. The claims are improperly joined as the claimed methods require the use and detection of distinct target molecules – i.e., the genes of hCG-β, hPL, hCRH, KISS1, TPF12, PLAC1 and GAPDH. A reference against one target molecule would not be a reference against the other target molecule. Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because the claims do not recite proper species. Upon election, Applicants are required to amend the claims to set forth only the elected inventive groups.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11, drawn to methods for diagnosing pre-eclampsia, classified in Class 435, subclass 6.

II. Claim 12, drawn to kits comprising primers and a control representing the amount of mRNA encoding a protein in the blood of an average non-preeclamptic pregnant woman, classified in Class 536, subclasses 23.5 and 24.33.

III. Claims 13-23, drawn to methods for detecting a fetus with trisomy 18, classified in Class 435, subclass 6.

IV. Claims 24 and 36, drawn to kits comprising primers and a control representing the amount of mRNA encoding a protein in the blood of an average

pregnant woman with a chromosomally normal fetus, classified in Class 536, subclasses 23.5 and 24.33.

V. Claims 25-35, drawn to methods for detecting a fetus with trisomy 21, classified in Class 435, subclass 6.

VI. Claims 37-46, drawn to methods for diagnosing pre-term labor, classified in Class 435, subclass 6.

VII. Claim 47, drawn to kits comprising primers and a control representing the amount of mRNA encoding a protein in the blood of an average pregnant woman who delivers at term, classified in Class 536, subclasses 23.5 and 24.33.

VIII. Claims 48-55, drawn to methods for detecting pregnancy, classified in Class 435, subclass 6.

IX. Claim 56, drawn to kits comprising primers and a control representing the amount of mRNA encoding a protein in the blood of an average non-pregnant woman, classified in Class 536, subclasses 23.5 and 24.33.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions I, III, V, VI, and VIII are drawn to patentably distinct methods having different outcomes and objectives. The claims of invention I are drawn to methods for diagnosing pre-eclampsia in a pregnant woman. The claims of invention III are drawn to methods for detecting a fetus having trisomy 18. The claims of invention V are drawn to methods for detecting a fetus having trisomy 21. The claims of invention VI are drawn to methods for identifying a pregnant woman who will have pre-term labor. The claims of invention VIII are drawn to methods for identifying a woman as being pregnant. The

conditions of pre-eclampsia, pre-term labor and pregnancy of a woman and the conditions of trisomy 18 and trisomy 21 of a fetus are distinct from one another with respect to their etiologies and outcomes. Accordingly, the detection of each of these conditions is patentably distinct from one another.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case, the method of invention I can be performed using a different product, such as probes to the mRNA. Further, the kits can be used in materially distinct processes such as in general methods for detecting mRNA expression to, for example, determine expression patterns in different tissues or in methods for detecting patentably distinct conditions.

Inventions I and IV, VII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case, the kits of inventions IV, VII and IX are not required to practice the method set forth in invention I.

Inventions II, IV, VII and IX are drawn to patentably distinct products, each comprising products having a different structure and effect. The kits of invention II comprise a control representing the amount of mRNA encoding a protein in the blood of an average non-preeclamptic pregnant woman The kits of invention IV comprise a

control representing the amount of mRNA encoding a protein in the blood of an average pregnant woman with a chromosomally normal fetus. The kits of invention VII comprise a control representing the amount of mRNA encoding a protein in the blood of an average pregnant woman who delivers at term. The kits of invention IX comprise a control representing the amount of mRNA encoding a protein in the blood of an average non-pregnant woman. While each of the controls comprise nucleic acids, the controls are not considered to be of a similar nature because each of the controls have a different composition and effect. Accordingly, each of the kits is patentably distinct from one another.

Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case, the method of invention III can be performed using a different product, such as probes to the mRNA. Further, the kits can be used in materially distinct processes such as in general methods for detecting mRNA expression to, for example, determine expression patterns in different tissues or in methods for detecting patentably distinct conditions, such as trisomy 21.

Inventions III and II, III and VII, and III and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP

806.04, MPEP 808.01). In the instant case, the kits of inventions II, VII and IX are not required to practice the method set forth in invention III.

Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case, the method of invention V can be performed using a different product, such as probes to the mRNA. Further, the kits can be used in materially distinct processes such as in general methods for detecting mRNA expression to, for example, determine expression patterns in different tissues or in methods for detecting patentably distinct conditions, such as trisomy 18.

Inventions VI and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case, the method of invention VI can be performed using a different product, such as probes to the mRNA. Further, the kits can be used in materially distinct processes such as in general methods for detecting mRNA expression to, for example, determine expression patterns in different tissues or in methods for detecting patentably distinct conditions.

Inventions VI and II, VI and IV, and VI and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case, the kits of inventions II, IV and IX are not required to practice the method set forth in invention VI.

Inventions VIII and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case, the method of invention VIII can be performed using a different product, such as probes to the mRNA. Further, the kits can be used in materially distinct processes such as in general methods for detecting mRNA expression to, for example, determine expression patterns in different tissues or in methods for detecting patentably distinct conditions.

Inventions VIII and II, VIII and IV, and VIII and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case, the kits of inventions II, IV and VII are not required to practice the method set forth in invention VIII.

Sequence Election Requirement Applicable to Each Invention

4. The claims have been presented in improper Markush format, as distinct products and distinct methods are improperly joined by the claims. The claims are improperly

joined as the claimed methods of inventions I, III, V, VI and VIII require the detection of distinct genes of hCG-β, hPL, hCRH, KISS1, TPF12, PLAC1 and GAPDH and the kits of inventions II, IV, VII and IX require primers to the distinct genes of hCG-β, hPL, hCRH, KISS1, TPF12, PLAC1 and GAPDH. Each gene consists of a different nucleotide sequence, has a different melting temperature, a different specificity of hybridization and encodes for a protein having a distinct biological activity. For example, gene encoding hCG-β is chemically, structurally and functionally distinct from a gene encoding hPL. A search for primers that detect a gene encoding hCG-β would not be co-extensive with a search for primers which detect a gene encoding hPL. Further, a finding that primers that detect a gene encoding hCG-β, for example, are novel and unobvious over the prior art would not necessarily extend to a finding that primers that detect a gene encoding hPL also novel and unobvious over the prior art. Similarly, a finding that an primers that detect a gene encoding hCG-β are anticipated or obvious over the prior art would not necessarily extend to a finding that primers that detect a gene encoding hPL also anticipated or obvious over the prior art.

Accordingly, the hCG-β, hPL, hCRH, KISS1, TPF12, PLAC1 and GAPDH are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Applicant is advised that this is a restriction requirement and should **not** be construed as an election of species.

In response to this restriction requirement, applicant should elect one gene or one particular combination of genes selected from the group consisting of hCG-β, hPL, hCRH, KISS1, TPF12, PLAC1 and GAPDH.

5. These inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter. Further, inventions I-IX require different searches that are not co-extensive. For instance, a search for the methods for diagnosing pre-eclampsia is not co-extensive with a search nucleic acids of invention I is not co-extensive with a search for methods for diagnosing trisomy 18, trisomy 21, pre-term labor or pregnancy. Additionally, a search for each of kits is not co-extensive with one another. Further, a finding that the method of invention I is anticipated or obvious over the prior art would not necessarily extend to a finding that the method of inventions III, V, VI or VIII or the kits of inventions II, IV, VII or IX were also anticipated or obvious over the prior art. Similarly, a finding that the method of invention I is novel and unobvious over the prior art would not necessarily extend to a finding that the methods of invention III, V, VI, or VIII or the kits of inventions II, IV, VII or IX are also novel and unobvious over the prior art. Accordingly, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. ə 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one

claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in

accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)-272-0735.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

Carla Myers
March 20, 2006

CARLA J. MYERS
PRIMARY EXAMINER